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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,467	04/09/2001	Hiroshi Shinoki	JG-SIK-5063/500676.20003	8683

7590 12/29/2003
REED SMITH LLP
375 Park Avenue
New York, NY 10152

EXAMINER

SIEW, JEFFREY

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/829,467

Applicant(s)

SHINOKI ET AL.

Examiner

Jeffrey Siew

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7,9,13,15,17,19,27 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7,9,13,15,17,19,27 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Applicant Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

1. The response filed 11/25/03 has been considered. In light of the applicant's unintentional mistake, the office has withdrawn the finality of the last action to be replaced with the finality of this office action.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY THE AMENDMENT

Claim Objections

2. Claim 9 depends on a later claim. Claims should depend on preceding claims. Correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A) Claim 11 is indefinite because it is unclear as to which claim it depends on.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1,3,7,9,13,15,17, 27 & 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brush et al (US5,986,086 Nov. 16, 1999) in view of Haugland et al (US5,719,031 Feb 17, 1998)

Brush teach a fluorescent nucleotide represented by formula A-B-C (abstract) where A represents a residue of natural or synthetic nucleotide (see col. 3 lines 50-60) and binds to B at base moiety where B is a divalent linking group or single bond (see col. 3 lines 35-50) and C represents a monovalent group derived from fluorescent dye have 0 sulfonic acid group or phosphoric acid group (see all figures and also col.2 lines 5, col.2 line 33 nonsulfonated cyanine

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dye). They teach that X and Y are each independently selected from group consisting O,S (see abstract). They teach that m is an integer 1,2 or 3 (see abstract Brush term is r for the claimed m). They teach R^1 and R^2 each independently represent a hydrogen atom or alkyl group capable of covalently binding to B (see abstract). They teach R^4 is hydrogen H and equivalent R^3 R^9 R^8 are hydrogen or R^5 is hydrogen (see abstract and figure). Brush also teaches of sulfonated cyanines (see col. 1 lines 53). They also teach that B may be sulfide or amine bond (see col.3 line 39). They also teach R^1 with carboxyl groups (see col.3 lines 15-19).

Brush et al do not teach having a water soluble group other than a sulfonic acid group, phosphoric acid or carboxylic group.

Haugland et al teach using sulfanamide in the dye to attach to nucleotide (see whole doc. esp. col. 7 line 35).

One of ordinary skill in the art would have been motivated to apply Haugland et al's teaching of sulfanamide into Brush fluorescent dye in order to attach the dye to the nucleotide. Haugland states that sulfanamide or amine successfully bound the oligonucleotide to the fluorophore. It would have been prima facie obvious to apply Haugland et al's successful use of sulfanamide to attach dyes to oligonucleotides in order to successfully attach fluorescent dyes to Brush et al's nucleotide.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brush et al (US5,986,086 Nov. 16, 1999) in view of Haugland et al (US5,719,031 Feb 17, 1998) in further view of Mao et al (Oct 10, 2000 102(e) date 9/23/1997).

The teachings and suggestions of Brush et al and Haugland et al are described previously.

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Brush et al do not teach aminoallyl linkage.

Mao et al teach aminoallyl linkage in binding dye to nucleotides (see col.16 line 64).

One of ordinary skill in the art would have been motivated to apply Mao et al's aminoallyl linkage to Brush et al's dye in order to provide stable bond. As Mao et al teach the successful use of aminoallyl bonds to attach dyes, it would have been prima facie to apply the aminoallyl linkage to Brush et al's dye in order to create a strong link to the nucleotide.

7. The response filed 11/21/03 has been fully considered and deemed not persuasive. The response states that Huagland et al use sulfonamide as a spacer or linker to attaching a functional group whereas the present invention is drawn to not using it as a linkage but rather as a water soluble group. The response then argues the unexpected properties of the benefits of water soluble group instead of linkage. One criteria for determining unexpected results is the nexus between the unexpected results and the claims (see 716.01b). The claims read so broadly and do not exclude the usage of sulfonamide as a linkage. The claims would still encompass Huagland et al's teaching. The rejections are maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


CONCLUSION

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

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Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.


JEFFREY SIEW
PRIMARY EXAMINER

December 20, 2003

ATTY. DOCKET: JG-SIK-5063/500676.20003

Please enter the following amendments.

AMENDMENTS TO THE CLAIMS:

1. (currently amended) A fluorescent nucleotide represented by the formula: A-B-C, wherein A represents a residue of natural or synthetic nucleotide, oligonucleotide, polynucleotide, or derivative thereof, and binds to B at a base moiety in said residue; B represents a divalent linking group or a single bond; and C represents a monovalent group derived from a fluorescent dye having no sulfonic acid group and no phosphoric acid group in a molecule, and having a ~~water-soluble group other than a sulfonic acid group~~ sulfonamide group or a lower alcohol group, a phosphoric acid group, or a carboxylic acid group in said molecule.

2. Cancelled.

3. (original) The fluorescent nucleotide according to claim 1, wherein the fluorescent dye is a cyanine, merocyanine, or styryl fluorescent dye.

4. Cancelled.

5. Cancelled.

6. Cancelled.

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